



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant : 09/774.284  
Filed : Nochumson  
TC/AU : 01/29/2001  
Examiner : 1623  
Howard Owens Jr.  
  
Docket No. : 213-0060US  
Customer No. : 25746

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Dear Sirs and Mesdames:

Applicant desires to bring to the attention of the Examiner the following references listed on the attached Information Disclosure Statement, Form PTO 1449. A copy of each of the references is enclosed in compliance with 37 CFR § 1.97 and 1.98. Submission of this Information Disclosure Statement should not be construed as a representation that a search has been made or that no other material information as defined in 37 C.F.R. 1.56(a) exists. This submission is not intended to constitute an admission that any patent, publication or other information referred to herein is "prior art" to the invention disclosed unless specifically so designated. The right is reserved to antedate any item under 37 C.F.R. 1.131.

- No fee is required as the present Information Disclosure Statement submitted under 37 CFR §1.97(b) is being filed within three months of the filing of a national application or before the mailing date of a first Office Action on the merits, whichever event occurs last.
- The present Information Disclosure Statement submitted under 37 C.F.R. 1.97(c) is being filed after three months of the filing of a national application or after the mailing date of a first Office Action on the merits, whichever occurred last but before the mailing date of either:
1. a Final Action under 37 C.F.R. 1.113, or
  2. a Notice of Allowance under 37 C.F.R. 1.311, whichever occurs first.

Also submitted herewith is:

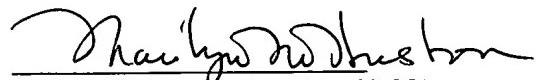
- a statement as specified in 37 C.F.R. 1.97 (e): **OR**
- a fee transmittal authorizing debit of Deposit Account No. **50-1922** in the amount of \$180 as set forth in 37 C.F.R. 1.17 (p) for submission of an Information Disclosure Statement under 37 C.F.R. 1.97(c).

Serial No.: 09/174,284  
Attorney Docket No.: 213-0060 US  
IDS Transmittal

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It is not believed that any further fees are required but should additional fees be required for the consideration of this IDS please consider this a request for consideration under the appropriate rule and an authorization for the Assistant Commission to charge and/ or credit Deposit Account No. 50-1922 should any additional fees be required or overpayment made.

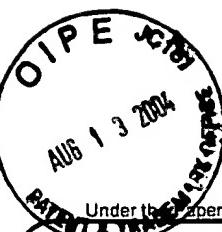
Respectfully submitted,



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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1

of 7

**Complete if Known**

Application Number	09/774,284
Filing Date	01/29/2001
First Named Inventor	Samuel Nochumson
Art Unit	1623
Examiner Name	Howard Owens Jr.

Attorney Docket Number 213-0060US

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> ( <i>if known</i> )			
1	US-	3,928,642	12/23/1975	Hubert et al.	
2	US-	4,314,974	02/09/1982	Libby et al.	
3	US-	4,450,103	05/22/1984	Konrad et al.	
4	US-	4,462,940	07/31/1984	Hanisch et al.	
5	US-	4,621,061	11/04/1986	Puehler et al.	
6	US-	4,780,210	10/25/1988	Hsia	
7	US-	4,900,677	02/13/1990	Hewitt	
8	US-	4,997,932	03/05/1991	Reardon et al.	
9	US-	5,057,426	10/15/1991	Henco et al.	
10	US-	5,096,818	03/17/1992	DeBonville	
11	US-	5,208,160	05/04/1993	Kikyotani et al.	
12	US-	5,256,294	10/26/1993	van Reis	
13	US-	5,300,433	04/05/1994	Hrinda et al.	
14	US-	5,561,064	10/01/1996	Marquet et al.	
15	US-	5,707,812	01/13/1998	Horn et al.	
16	US-	5,990,301	11/23/1999	Colpan et al.	
	US-				
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**FOREIGN PATENT DOCUMENTS**

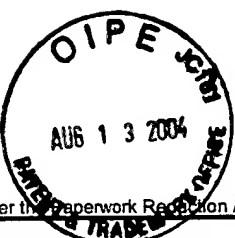
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> ( <i>if known</i> )				
W1	WO 87/07645		12/17/1986	Coates et al.		
W2	WO 89/01035		02/09/1989	Ansorge et al.		
W3	WO 95/21177		08/10/1995	Colpan et al.		
W4	WO 97/23601		07/03/1997	Wan et al.		
W5	EP 0 240 191		10/07/1987	Masafumi et al.		
W6	EP 0 376 080		07/04/1990	Schneider		

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<b><i>Complete if Known</i></b>	
Application Number	09/774,284
Filing Date	01/29/2001
First Named Inventor	Samuel Nochumson
Art Unit	1623
Examiner Name	Howard Owens Jr.
Attorney Docket Number	213-0060US

Sheet 2

of 7

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		Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
	W7	EP 0 431 905	06/12/1991	Nishi et al.		
	W8	JPA 58013519	01/26/1983	Niwa et al.		
	W9	WO 99/63076	12/09/1999	Musil et al.		
	WA	AU 723817	03/08/1998	Kuhne		
	WB	WO 96/08500	03/21/1996	Colpan		

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<b>Application Number</b>	09/774,284				
<b>Filing Date</b>	01/29/2001				
<b>First Named Inventor</b>	Samuel Nochumson				
<b>Art Unit</b>	1623				
<b>Examiner Name</b>	Howard Owens Jr.				
<b>Sheet</b>	<b>3</b>	<b>of</b>	<b>7</b>	<b>Attorney Docket Number</b>	<b>213-0060US</b>

**NON PATENT LITERATURE DOCUMENTS**

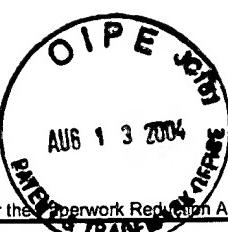
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	P1	CARLSON et al., "Mechanical Disruption of Escherichia Coli For Plasmid Recovery," Biotechnology and Bioengineering, 48: 303-315, 1995. John Wiley & Sons, Inc., USA.	
	P2	CHANDRA, G. et al., "Large-Scale Purification of Plasmid DNA by Fast Protein Liquid Chromatography Using a Hi-Load Q Sepharose Column," Analytical Biochemistry, 203: 169-172, 1992. Academic Press, USA.	
	P3	COPPELLA, S. et. al., "Isolation of High-Molecular-Weight Nucleic Acids for Copy Number Analysis Using High-Performance Liquid Chromatography," Journal of Chromatography, 402: 189-199, 1987. Elsevier Science Publishers B.V., The Netherlands.	
	P4	Data Sheet TMAE	
	P5	FILTRON Membrane Separation Products Brochure, 1995/96, 1-17.	
	P6	Fractogel EMD Process Media	
	P7	GOEBEL, U. et al., "Quantitative Electroelution of Oligonucleotides and Large DNA Fragments from Gels and Purification by Electrodialysis," Journal of Biochemical and Biophysical Methods, 14: 245-260, 1987. Elsevier Science Publishers B.V., The Netherlands.	
	P8	GRAF et al., "Performance of a Tubular Microporous Membrane Filter Used for In situ Sampling of Mammalian Cell Culture Medium," Biotech. Tech., 5(3): 183-186, April 1991. Kluwer Academic Publishers, The Netherlands.	
	P9	Guide to Tentacle-Biochemistry <a href="http://www.chromatography.co.uk/products/bio/summary.htm">www.chromatography.co.uk/products/bio/summary.htm</a>	
	P10	HANCHER et al., "Evaluation of Ultrafiltration Membranes with Biological Macromolecules," Chemical Abstracts, 79. abstract no. 88983n, October 1973. American Chemical Society, USA.	

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

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<b>Application Number</b>	09/774,284
<b>Filing Date</b>	01/29/2001
<b>First Named Inventor</b>	Samuel Nochumson
<b>Art Unit</b>	1623
<b>Examiner Name</b>	Howard Owens Jr.
<b>Attorney Docket Number</b>	213-0060US

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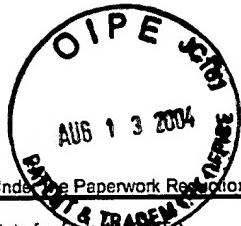
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	P11	HEINZEL et al., "Autonomous DNA Replication in Human Cells is Affected by the Size and the Source of the DNA," Molecular and Cellular Biology, 11(4): 2263-2272, 1991. ASM Press, USA.	
	P12	HIRT, B., "Selective Extraction of Polyoma DNA from Infected Mouse Cell Cultures," Journal of Molecular Biology, 26: 365-369, 1967. Academic Press, USA.	
	P13	HORN, N. et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," Human Gene Therapy, 6: 565-573, May 1995. Mary Ann Liebert, Inc. Publishers, USA.	
	P14	HOU, K.C. et al., "Endotoxin Removal by Anion-Exchange Polymeric Matrix," Biotechnology and Applied Biochemistry, 12: 315-324, 1990. Portland Press, USA.	
	P15	HUBBLE et al., "Alginate Ultrafiltration Membranes," Biotechnology Letters, 7 (4): 273-276, April 1985. Kluwer Academic Publishers, The Netherlands.	
	P16	KAHN et al., "Purification of Plasmid DNA by Tangential Flow Filtration," Biotechnology and Bioengineering, 69(1): 101-106, 2000. John Wiley & Sons, Inc., USA.	
	P17	LIS et al., "Size Fractionation of Double-Stranded DNA by Precipitation with Polyethylene Glycol," Nucleic Acids Research, 2(3): 383-389, 1975. ISSN 0304-1048 IRL Press, USA.	
	P18	MANIATIS, "Large-Scale Isolation of Plasmid DNA," Molecular Cloning - A Laboratory Manual," 85, 87, 90, and 91, 1982. Cold Spring Harbor Laboratory Press, USA.	
	P19	MARASHI F. et al., "Use of Ultrafiltration Microconcentrators in the Concentration and Desalting of DNA," BioTechniques, May/June 1985: 238-240.	
	P20	MARQUET et al., "Characterization of Plasmid DNA Vectors for Use in Human Gene Therapy, Part 1, BioPharm, 42-55, 1992. Biotechniques Press Publishing, USA.	

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Substitute for form PTO-903

**Complete if Known**

<b>Application Number</b>	09/774,284
<b>Filing Date</b>	01/29/2001
<b>First Named Inventor</b>	Samuel Nochumson
<b>Art Unit</b>	1623
<b>Examiner Name</b>	Howard Owens Jr.

## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

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Sheet	5	of	7	Attorney Docket Number	213-0060US
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### NON PATENT LITERATURE DOCUMENTS

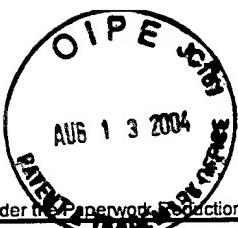
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	P21	MARQUET et al., "Process development for the manufacture of plasmid DNA vectors for use in gene therapy," BioPharm, 8(7): 34, 1995.	
	P22	MICHAELS et al., Wayne P. Olson, Editor, "Separations Technology, Pharmaceutical and Biotechnology Applications," 57-194, 1995. Interpharm Press, Inc., USA.	
	P23	MONTBRIAND, P.M. et al., "Improved Method for the Removal of Endotoxin from DNA," Journal of Biotechnology 44:43-46, 1996. Elsevier Sci. Pub. B.V., The Netherlands.	
	P24	MORELLE, G., "A Plasmid Extraction Procedure on a Miniprep Scale," Focus 11: 7-8, 1989. Life Technologies, Inc., USA.	
	P25	Pall KLEENPAK Ultipor N66 Filter Assembly Brochure	
	P26	Pall KLEENPAK Ultipor N66 Membrane Filter Guide	
	P27	PAPAMICHAEL et al., "Continuous Aqueous Phase Extraction of Proteins: Automated Processing and Recycling of Process Chemicals," J. Chem. Tech. Biotechnology, 54: 47-55, 1992. Society of Chemical Industry, Great Britain.	
	P28	PRAZERES et al., "Large-Scale Production of Pharmaceutical-Grade Plasmid DNA for Gene Therapy: Problem and Bottlenecks," Trends Biotechnol., 17: 169-174, 1999. Elsevier Sci. Pub. B.V., The Netherlands.	
	P29	REMBHOTKAR et al., "Large Scale Preparation of Bacteriophage Lambda by Tangential Flow Ultrafiltration for Isolation of Lambda DNA," Anal. Biochem., 176: 373-374, May 1989. Elsevier Sci. Pub. B.V., The Netherlands.	
	P30	SHARMA, S.K., "Endotoxin Detection and Elimination in Biotechnology," Biotechnology and Applied Biochem. 8: 5-22, 1986. Academic Press Inc., USA.	

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<b>Sheet</b>	6	<b>of</b>	7	<b>Attorney Docket Number</b>	213-0060US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	P31	SOLUM, N.O., "The Coagulogen of Limulus Polyphemus Hemocytes. A Comparison of the Clotted and Non-Clotted Forms of the Molecule." Thrombosis Research, 2: 55-70, 1973. Academic Press Inc., USA.	
	P32	SONG et al., "Theory of Concentration Polarization in Crossflow Filtration," J. of Chem. Society, Faraday Transactions, 91(19): 3389-3398, 1995. Chemical Society Press, USA.	
	P33	TALMADGE, K.W. et al., "Efficient Endotoxin Removal with a New Sanitizable Affinity Column: Affi-Prep Polymyxin," Journal of Chromatography, 476: 175-185, 1989. Elsevier Scientific Pub. B.V., The Netherlands.	
	P34	THEODASSIOU et al., "The processing of a plasmid-based gene from E. coli. Primary recovery by filtration..," Bioprocess Engineering, 16: 175-183, 1997. Springer-Verlag, Germany.	
	P35	THOMPSON, J.A., "A Review of High-Performance Liquid Chromatography in Nucleic Acids Research. III. Isolation, Purification, and Analysis of Supercoiled Plasmid DNA." BioChromatography, 1(2): 68-80, 1986. Eaton Publishing Co., USA.	
	P36	VANHAECKE, E. et al., "Endotoxin Removal by End-Line Filters," Journal of Clinical Microbiology, 27(11): 2710-2712, 1989. ASM Press, USA.	
	P37	VEIDE et al., "Continuous extraction of beta-D-galactosidase from E. coli in an aqueous two-phase system: effects of biomass concentration on partitioning and mass transfer," Enzyme Microb. Technol., 6: 325-330, 1984. Buttersworth & Co. Ltd., UK.	
	P38	WEISS, A.R. et al., "Clearance of Endotoxin from Solution by Adsorptive Filtration with Sartobind Membrane Adsorbers," Sartorius Corp., Developing Methods #7.	
	P39	XP02216258 "Plasmid Midi and Maxi Preparations," Diagen: The Qiagenologist/Application Protocols: 3rd Ed. Nov. 1990, pg. 13-14.	
	P40	YATES et al., "Stable Replication of Plasmids Derived from Epstein-Barr Virus in Various Mammalian Cells," Nature, 313:812-815, 1985. Nature Publishing Group, UK.	

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**Complete if Known**

<b>Application Number</b>	09/774,284
<b>Filing Date</b>	01/29/2001
<b>First Named Inventor</b>	Samuel Nochumson
<b>Art Unit</b>	1623
<b>Examiner Name</b>	Howard Owens Jr.

Attorney Docket Number 213-0060US

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	P41	ZASLOFF et al., "A New Method for the Purification and Identification of Covalently Closed Circular DNA Molecules," Nucleic Acids Research, 5: 1139-1153, 1978. Oxford University Press, UK.	
	P42	DURLAND et al., " Manufacturing and quality control of plasmid-based gene expression systems." Advanced Drug Delivery Reviews, 30: 33-48, 1998. Elsevier Scientific Pub. B.V., The Netherlands.	
	P43	KASAI, K-i., "Size-dependent chromatographic separation of nucleic acids,"Journal of Chromatography 618:203-221, 1993. Elsevier Scientific Pub. B.V., The Netherlands.	
	P44	Maa et al., Abstract, "Rapid high-performance liquid chromatography of nucleic acids with poly-styrene-based micropellicular anion exchangers," Journal of Chromatography A, 508: 61-73, 1990. Elsevier Scientific Pub. B.V., The Netherlands.	
	P45	McLaughlin et al., "Resolution of RNA Using High-Performance Liquid Chromatography," Journal of Chromatography, 418: 51-72, 1987. Elsevier Scientific Pub. B.V., The Netherlands.	
	P46	Merion et al., "Purification of Supercoiled Plasmids from Crude Cell Lysates Using High Performance Anion Exchange Chromatography," BioTechniques 7(1): 60-67, 1989.	
	P47	Ohmiya et al., Abstract, "Separation of DNA fragments by high-resolution ion-exchange chromatography on a nonporous QA column," 189(1): 126-130, 1990. Academic Press, USA.	
	P48	Sartopure GF Information Sheet from Sartorius.	

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